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EXAMINER	
GAMETT, DANIEL C	

ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,595	SIPPEL ET AL.	
	Examiner	Art Unit	
	Daniel C Gamett	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-73* is/are pending in the application.

4a) Of the above claim(s) *44-60,64,65 and 71* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-43,61-63,67-70,72 and 73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *Aug 13, 2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Claims 1-43, 61-63, 67-70, 72, and 73 in the reply filed on November 1, 2004 is acknowledged. The traversal is on the ground(s) that "all the claims in the application involve related subject matter, e.g., a fusion protein comprising the recited domains. A search would therefore comprise overlapping subject matter, and it would not be an undue burden on the examiner to carry out a search". This is not found persuasive because many claims do not, in fact, involve the fusion protein comprising the recited domains. None of Groups VII-XII is drawn to said fusion protein; these claims are drawn to various compounds, ligands, polypeptides, DNA molecules and methods of use of same. With regard to the remaining claims, while Groups I-VI each recite a fusion protein, they do so in such a variety of embodiments—alternatives with different types of polypeptide in positions 2 (various known receptors, unknown proteins being tested, able or unable to bind ligand) or 3 (various Ras proteins and exchange factors, positively or negatively regulated by ligand binding at domain 2), each possibly comprising a 4^{th} domain as defined in claim 4, and each constructed for different purposes, so as to make search and examination impossible without restriction and election of species. In this regard, it is noteworthy that the preparer of the International Preliminary Examination Report found it impossible to establish a search report for any of the claims in this application due to "lack of clarity". Claims 1-43, 61-63, 67-70, 72, and 73 together represent a product (the fusion protein), a method of making and methods of using said product. The methods of use claims, 36-43, 61-63, 67-70, 72, and 73 were grouped together because the purposes and procedures of the claimed assays

("suitability of a test substance as ligand", screening for unknown ligands, or identifying a ligand that binds to a nuclear receptor) seem to be nearly equivalent to each other and thus form a group that is distinct from the analytical methods of Groups II-IV or the protein identification methods of Groups V and VI.

2. The requirement is still deemed proper and is therefore made FINAL.

3. Applicant's election of species: steroid receptor (a) for the second domain; constitutively active ras protein with (1) ras derived amino acid sequence for the third domain; and (n) activate transcription factors for genes which are not essential for cell reproduction or expression of a reporter gene for the endpoint species, is further acknowledged. Claims 11-13, 29, 38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species. Claims 1-10, 14-28, 30-37, 39-43, 61-63, 67-70, 72, and 73 will be examined only to the extent that they read on elected species.

Objections to the Disclosure

4. The disclosure is objected to because of the following informalities: The specification is not divided into sections with appropriate headings and content. Specifically missing are:

- Background of the Invention: See MPEP § 608.01(c), which should be in two parts: Field of the Invention and Description of the Related Art (or "Background Art");
- Brief Summary of the Invention: See MPEP § 608.01(d);
- Brief Description of the Drawing(s): See MPEP § 608.01(f); and
- Detailed Description of the Invention: See MPEP § 608.01(g).

Appropriate correction is required.

Claim Rejections 35 U.S.C. 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-43, 61-63, 67-70, 72, and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim is drawn to a fusion protein having at least three domains. The definitions for these domains are unclear for several reasons. Firstly, all three domains are defined by functional criteria with no structural limitations and therefore the definitions do not convey sufficient information to apprise the skilled artisan as to what is essential and what is optional. For example, almost any polypeptide sequence might meet the limitation "has *or presumably has* a ligand-binding function of a nuclear receptor", recited for the second domain. This is also a problem for the third domain, which has the functional limitation "has an activity able to activate a signal pathway connected to a Ras protein in a cell." Applicant apparently envisions proteins that interact directly with Ras, but the phrase "an activity able to activate a signal pathway connected to a Ras protein" encompasses much more. Exactly how closely connected to Ras must this pathway be? Would the kinase domain of a transmembrane receptor qualify? What about enzymes normally downstream in the Ras pathway, such as MEKK, MEK, or MAPK? Claims 2-43, 61-63, 67-70, 72, and 73 are rejected for being dependent on indefinite claim 1 and for failing to resolve the issues raised above.

7. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 5 recites the broad recitation "a membrane-localization signal", and the claim also recites "in particular a famesylation signal, myristylation signal or prenylation signal or transmembrane domain" which is the narrower statement of the range/limitation. Similar examples of a broad range or limitation together with a narrow range or limitation exist in claims 10, 22, 30, 33, and 42, the specifics of which are omitted here for the sake of brevity.

8. Claim 23 recites the limitation " characterized in that in the absence of fusion protein at least under certain conditions a signal pathway connected to a Ras protein cannot be activated in the cell." in "A cell as claimed in claim 19". There is insufficient antecedent basis for this limitation in the claim. Claim 19 is drawn to "A cell comprising a fusion protein as claimed in claim 1". There is no "absence of fusion protein".

9. Claim 72 is drawn to "A method for identifying a ligand for a binding section of a receptor" and recites the cells of claim 36 and so it was grouped with the other elected claims. Claim 72 also recites several aspects of non-elected claims, "protein having a ligand-binding function of a receptor", for example. This claim seems to be an attempt to encompass all, or most, of the various embodiments and uses of the fusion protein of claim 1 into a single claim. As such it is very confusing. The Examiner concurs with the preparer of the International Preliminary Examination Report, who stated that this claim "cannot be interpreted".

10. Claim 73 recites the limitation "a composition as claimed in claim 72". There is insufficient antecedent basis for this limitation in the claim. Claim 72 does not seem to recite a composition.

11. The Examiner recommends that if Applicant chooses to amend, ALL elected claims should be reviewed for clarity. In this regard, the following excerpt from the International Preliminary Examination Report is particularly significant: "A further lack of clarity is introduced into the claims by the fact that several times various alternatives are described, but then retracted in part, and by the fact that back-references are introduced and changed at the same time, so that ultimately it is no longer clear to what each option does or does not refer."

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-43, 61-63, 67-70, 72, and 73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. All claims depend from Claim 1, which is drawn to a fusion protein (in fact, a genus of fusion proteins) having at least three domains. To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, each of the three domains is defined by functional criteria with no structural limitations. An example of a functional fusion protein is provided, but precise information as to the structure of said protein cannot be found anywhere in the disclosure. The schematic diagram (figure 2) does not provide adequate description—it merely labels the domains. The amino acid sequence is not revealed. Source sequences for the first and third domains are not identified or referenced. The second domain is identified as amino acids 282-595 of the human estrogen receptor and even that recitation is not adequate because it is not accompanied by a submitted sequence identified by a SEQ. ID. NO. See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The functional limitations allow for a broad range of structures. For example, the second domain "has or presumably has a ligand-binding function of a nuclear receptor". This generic description encompasses many possible structures, especially in view of the specification (p. 5, line 20-p.6 line15) wherein

"ligand" is defined as including binding partners for nuclear receptors which elicit a conformational change, including "conformational changes like those taking place in vivo on binding of a natural ligand" (p. 5 lines 38-39), but also including "cases in which the conformational changes do not correspond, correspond only partly, to the conformational changes taking place on binding of a ligand occurring in vivo in the cell" (p. 6, lines 11-15). These definitions, together with the phrase "or presumably has" in claim 1, expand the genus of polypeptides that might occupy the second domain to include any protein that might undergo a conformational change upon binding to any partner. The most explicitly disclosed species, amino acids 282-595 of the human estrogen receptor, is not adequately described, as detailed above, and is not representative of this large genus, even considered together with several species implied in the specification. Furthermore, the specification states: "The meaning of the term "nuclear receptor" in the present context is moreover additionally also intended to extend to, for example, viral (including retroviral) non-membrane-associated receptors which likewise have the properties of being in inactive form without bound ligand but undergoing a conformational change on binding of their ligand and thus being converted into a so-called "active" form (p.6, lines 18-24). The specification neither discloses nor cites reference to a viral receptor that meets these limitations. Known virus receptors are cell surface (not nuclear) proteins (Tissue Tropism, *In*, Medical Microbiology, S. Baron, Ed., 4th Edition, 1996). Thus, this "example" does not provide a description of a nuclear receptor and only creates confusion as to what Applicant means by the term. Furthermore, Applicant appears to be attempting claim a receptor that is not currently known to exist but which might be discovered at some point in the future. Accordingly,

in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). The skilled artisan cannot envision, from the description provided in the instant application, the detailed chemical structure of the polypeptides encompassed by claim 1, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. The instant specification does not even provide that much information for the genus of fusion proteins in claim 1. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

13. Without written description of the fusion protein of claim 1, the embodiments in claims 2-14, the DNA (with no SEQ. ID. NO.), vectors, and transformed cells of claims 15-35, and the assays of Claims 36-43, 61-63, 67-70, 72, and 73 also lack written description.

14. Claims 1-43, 61-63, 67-70, 72, and 73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or the invention. As the essential component of all of these claims, the fusion protein of claim 1, lacks written description, one skilled in the art could not make the invention. Furthermore, while the specification does provide an example of how to use one preferred embodiment, specifically a fusion protein in which domain 1 comprises a myristylation signal, domain 2 is amino acids 282-595 of the human estrogen receptor, and domain 3 is human Ha-Ras (L61) lacking a CAAX box, this does not reasonably provide enablement for the multiple combinations of alternative polypeptides that may comprise the three domains. Therefore, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The instant fact pattern is similar to that in *In re Hyatt*, 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983), wherein a single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification at most disclosed only those means known to the inventors. When claims

depend on a recited property, a fact situation comparable to *Hyatt* is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. See also *Fiers v. Sugano*, 984 F.2d 164, 25 USPQ2d 1601 (Fed. Cir. 1993), and MPEP § 2164.08(a). Before addressing the specifics of the instant case, consider the following passage from Mattioni *et al.*, 1994, Methods in Cell Biology, Vol. 43, Chapter 16, p. 339, concerning regulation of protein activities by fusion to steroid binding domains: "The approach will only work if the protein of interest tolerates fusion to the rather large (about 300 amino acids) regulatory domain. It is often difficult to predict whether N- or C-terminal or even internal additions are compatible with the activity of the heterologous moiety." In the instant case, all of the elected claims depend from claim 1 which is drawn to a fusion protein having at least three domains. The following paragraphs will point out that the limitations recited in Claim 1 allow each of the three domains to be occupied by multiple alternative molecular entities. The functionality of this fusion protein is regulated by its second domain which is either a steroid binding domain or something very much like one generically described as "a ligand-binding function of a nuclear receptor". In view of Mattioni *et al.*, it should be evident that each embodiment of the claimed fusion protein needs to be characterized individually and that one working example is not enabling for the scope of the claims.

15. In Claim 1 of the instant case, the function of the first domain is "mediates membrane localization of the fusion protein in a cellular context". This functionality is provided by a myristylation signal in the example provided on pp.52-53 and in figure 2. The specification suggests other structures that may fulfill or augment this functionality, such as forms of lipid

modification (p.12, lines 11-16) and additional signal sequences such as those from GPCRs or yeast invertase (p.12, lines 35-39) and further points out that these alternatives will have variable suitability for use in various kinds of cells (p. 12, lines 18-39). The claimed fusion protein depends on proper membrane localization as well as proper interactions among its domains. The effect of varying the means of membrane localization is unpredictable, it may be different for each embodiment with alternative sequences in the second or third domains and for each cell in which the fusion protein is to be expressed. The skilled artisan would have to perform trial and error experimentation to make the claimed invention.

16. As recited in Claim 1, the second domain "has or presumably has a ligand-binding function of a nuclear receptor". This functionality is provided by amino acids 282-595 of the human estrogen receptor in the example provided on pp.52-53 and in figure 2. As noted above, the genus of molecules that may provide this function is very large. Even when the term "nuclear receptor" is limited to its standard meaning, such as the categories of receptor recited in claim 7, this genus is not adequately represented by the single enabled species, amino acids 292-595 of the human estrogen receptor. McMahon (2001, Methods in Enzymology Vol. 332) in a section beginning on p. 413, notes that while hormone binding domains from several types of nuclear receptor have been used to regulate the activity of heterologous proteins, there are some concerns that "can be resolved only empirically" among which are the expression of endogenous receptors and, notably, the "tightness of regulation" of any given fusion protein. Thus, each possible combination will need to be enabled individually. Furthermore, the claim is greatly broadened by the definition of ligand given in the specification (p. 5 lines 20-28): "the term "ligand" is intended to mean in the present context

only those binding partners for receptors and, in particular, nuclear receptors which elicit on binding to the ligand-binding section or receptor section of such receptor a conformational change which puts the third domain in the position of or, alternatively, prevents it from exerting its activity for activation of a signal pathway connected to a Ras protein in a cell." Thus "ligand" is itself functionally defined only in terms of activity in relation to the fusion protein and one cannot know if one has either a ligand or a "ligand-binding function of a nuclear receptor" until after the fusion protein is built and put to the test. This does not teach how to make the invention, it merely invites the skilled artisan to engage in trial and error in order to find a combination that works. Finally, the extension of the genus of "nuclear receptors" to include virus receptors (p.6, lines 18-24), exacerbates the lack of enablement. The ligands for virus receptors are, by definition, components of the virus particle and therefore are not soluble small molecules like estrogen. As noted above, known virus receptors are cell surface (not nuclear) molecules. Even if a nuclear virus receptor were known, it is difficult to imagine how said receptor would work in this context, considering that, as part of the claimed fusion protein, it would be localized to the inner surface of the plasma membrane. How would the ligand gain access except when the virus is already inside the cell?—a pathological condition which would complicate (to understate the case) readout of the desired end result.

17. The third domain "has an activity able to activate a signal pathway connected to a Ras protein in a cell, characterized in that when there is a lack of binding or, alternatively, when there is binding of a ligand to the second domain the third domain cannot exert activity to activate a signal pathway connected to a Ras protein in a cell". The example on pp.52-53 and

in figure 2 has human Ha-Ras (L61) providing the functionality of the former alternative, i.e. when there is a lack of binding of a ligand to the second domain the third domain cannot exert activity. It remains to be seen, however, if other potential occupants of domain three perform similarly. It also remains to be seen whether human Ha-Ras (L61) can be regulated similarly when either of the first or second domains are different from the ones in the example. Furthermore, there is no working example of the latter alternative, i.e. when there is binding of a ligand to the second domain the third domain cannot exert activity. This remains a theoretical prediction awaiting confirmation by experimentation.

18. Due to the large quantity of experimentation necessary to piece together fusion proteins and test them for the desired functionalities, the lack of direction/guidance presented in the specification regarding the structures that are required or optional for said construction, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which established the unpredictability of whether various combinations of multiple alternative polypeptides that may comprise the three domains will work together in the desired manner, and the breadth of the claims which fail to recite structural limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

19. Furthermore, Claims 2-43, 61-63, 67-70, 72, and 73 are rejected because they all depend on the product of Claim 1, which is not fully enabled as described above, and because the additional limitations these claims do not overcome the lack of enablement of claim 1. Specifically, enablement is not achieved by rearranging the order of the three domains (claim 2), specifying that the activity of the third domain is additionally regulated by the binding of

a protein complex (claim 3), adding a fourth domain (claim 4), specifying that domain 1 comprises a farnesylation signal, myristylation signal, or prenylation signal or transmembrane domain (claim 5), specifying that the second domain comprises an amino acid sequence of a naturally occurring nuclear receptor (claim 6), specifying the categories of nuclear receptor that may be used (claim 7) or by using a synthetic receptor designed by molecular modeling (claim 9). Indeed, these limitations only serve to accentuate the differences between the functional species and the breadth of the claimed genus. These differences are exacerbated by the phrase "or is derived therefrom" tagged to the end of claims 5,6, and 7 and by the proposal to genetically modify the sequence of the second domain (claim 8), which introduce the possibility of more variants that are not represented by the enabled species and are not supported in the specification. In claim 10, the third domain is a constitutively active Ras protein, which coincides with the enabled species, but this claim still permits variability in the first and second domains and thus it remains non-enabled.

Conclusion

20. No claims are allowed.

*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C Gamett, PhD, whose telephone number is 571 272 1853. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

DCG
Art Unit 1647
10 December 2004

ELIZABETH KEMMERER
PRIMARY EXAMINER